UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES TO: Barger, Case No. 1:13-cv-12619; Barnard, Case No. 1:13-cv-12738; Berry, Case No. 1:13-cv-12838; Davis, Case No. 1:13-cv-12426 Denson, Case No. 1:13-cv-12733 Minor, Case No. 1:13-cv-12836 Peay, Case No. 1:13-cv-12843 Pierce, Case No. :13-cv-12733 Redkevitch, Case No. 1:13-cv-12666 Schulz, Case No. 1:13-cv-12311 White, Case No. 1:13-cv-12734	MDL No. 2419 Master Docket No.: 1:13-md-2419 (RWZ)

Plaintiffs' Steering Committee's Response in Opposition to Motion to Dismiss Based Upon Asserted Failure to Comply With Tennessee Healthcare Liability Act Filed By The Saint Thomas Entities

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On January 10, 2014, Saint Thomas West Hospital, Saint Thomas Network, Saint Thomas Health, Ascension Health Alliance, and Ascension Health (collectively the "Saint Thomas Entities") filed a Rule 12(b)(6) motion to dismiss (Dkt. No. 779, and hereinafter the "Motion") along with a memorandum in support (Dkt. No. 780, hereinafter the "Memo in Support") seeking dismissal of approximately 25 cases for an alleged failure to comply with Tennessee Healthcare Liability Act, Tenn. Code Ann. § 29-26-101 *et. seq* (the "Healthcare Liability Act"). The plaintiffs' Steering Committee now files this Response in Opposition. Since the St. Thomas Entities' motion is similar to the Tennessee Defendants' motion to dismiss for failure to comply with the Tennessee Healthcare Liability Act (Dkt. No. 770), for the Court's convenience, issues addressed herein will not be separately briefed in the PSC's response to the Tennessee Defendant's Motion to Dismiss.

I. Introduction

Patients of the Saint Thomas Entities received epidural steroid injections containing contaminated MPA at the Saint Thomas Outpatient Neurosurgical Center ("Saint Thomas Clinic"). Because Saint Thomas Clinic was one of NECC's largest customers by volume, the fungal meningitis outbreak impacted patients of the Saint Thomas Clinic particularly severely.

Having failed to protect their patients from NECC's dangerous products, the Saint Thomas Entities now seek to avoid responsibility for their actions by obtaining dismissal of plaintiffs' claims on mere procedural trifles. The Saint Thomas Entities claim that plaintiffs - who originally *only* brought product liability claims under the Tennessee Products Liability Act, Tenn. Code Ann. § 29-28-101 *et seq* (the "Products Liability Act") – had to comply with the pre-suit notice (Tenn. Code Ann. § 29-26-121) and certificate of good faith (Tenn. Code Ann. § 29-26-122) requirements contained in Tennessee's Healthcare Liability Act, Tenn. Code Ann. § 29-

26-101, *et. seq*. (the "Healthcare Liability Act"). In other words, the Saint Thomas Entities attempt to impose health care liability requirements on product liability claims even though the Product Liability Act and the Healthcare Liability Act are separate and distinct statutes giving rise to separate and distinct claims.

The Saint Thomas Entities fail to cite a single judicial opinion in which requirements of the Healthcare Liability Act were applied to claims brought under the Products Liability Act. That dearth of authority is not surprising given that the plain language of the statutes indicates that Product Liability Act claims are not subject to the Healthcare Liability Act's pre-suit notice and certificate of good faith requirements. Furthermore, even if plaintiffs' product liability claims are subject to the requirements of the Healthcare Liability Act (which they are not), under Federal Rule of Civil Procedure 8(e), plaintiffs had an absolute right to plead Product Liability Act claims in the alternative.

In short, the Saint Thomas Entities' Motion is based on a flawed reading of both state substantive law and federal procedural law, and the Motion must be denied.

II. Procedural Background

On January 10, 2014, the Saint Thomas Entities filed the present Motion. Thereafter, the parties began a meet and confer related to the fact that the Motion raised individual issues that the PSC maintained should not be addressed at this stage in the litigation. At the March 13, 2014 status hearing, the PSC and counsel for the Saint Thomas Entities announced an agreement that extended the PSC's deadline to respond to the Motion while the parties continued to meet and confer on the global issues that should be addressed at this stage of the litigation.[1] On April 24, 2014, the parties submitted an assented to motion agreeing to hold in abeyance all individualized issues raised by the Motion and to only brief the following global issues raised by the Motion:

[1] *See* Dkt. No. 1028.

> (2) Whether the pre-suit requirements set forth in Tenn. Code Ann. § 29-26-121 apply to plaintiffs filing complaints alleging only claims styled as products liability claims and, if so, whether the failure to comply with such pre-suit requirements can be cured by a pleading amendment; and
>
> (3) Whether Tenn. Code Ann. § 29-26-122 requires that a plaintiff filing complaints alleging only claims styled as products liability claims file a certificate of good faith with the original complaint.[2]

Based on the PSC's review of the relevant cases identified in the Motion, these issues only apply to the cases identified in the case caption above.

III. Inconsistent Statutes Create Procedural Catch 22.

Because of certain inconsistencies between the temporal requirements of the Product Liability Act and the Healthcare Liability Act, many plaintiffs included product liability claims only in their initial complaints. They did not include healthcare liability claims in their initial complaints because those claims were not yet ripe.

Under the Tennessee Products Liability Act, arguably, Tennessee's one year statutory limitations period begins to run on the date when a plaintiff discovers or reasonably should discover that he or she was injured by an unreasonably dangerous or defective product.[3] The Tennessee Product Liability Act does not require any pre-suit notice before litigation is commenced. Under the Healthcare Liability Act, in contrast, the statute of limitations expires one year and 120 days after a party discovers an injury related to the provision of health care services and after a patient or her representative provides the healthcare provider with a

[2] *See* Dkt. No. 1100-1. This proposed order also contained one other issue to be briefed: whether pre-suit notice and a medical records release should have been sent to or for NECC and the Affiliated Defendants under the Healthcare Liability Act, but that issue only applies to a motion to dismiss filed by other defendants in Tennessee. Given the lack of merit to this argument, as explained in greater detail in the contemporaneously filed Response in Opposition to the Tennessee Defendants' Motion to Dismiss, it is not surprising that the Saint Thomas Entities do not raise this issue as a ground for dismissal in their Motion (even though the issue would apply equally to the Saint Thomas Entities).

[3] Tenn. Code Ann. § 29-28-103; and *McCroskey v. Bryant Air Conditioning Co*., 524 S.W.2d 487 (Tenn.1975).

particular pre-suit notice.[4] In other words, the Healthcare Liability Act prohibits the filing of healthcare liability claims unless and until a plaintiff provides the target healthcare provider with advance written notice of his or her intention to sue. That pre-suit notice must be given at least 60 days before suit is filed. If the plaintiff complies with that 60 day pre-suit notice requirement, then the one year statute of limitations applicable to all personal injury claims is extended by 120 days.[5]

Accordingly, one possible consequence of the incongruent temporal requirements applying to product liability claims and healthcare liability claims (read in the light *least* favorable to the plaintiff) is that the statute of limitations applicable to product liability claims can expire while claims under the Healthcare Liability Act are not yet ripe. Out of an abundance of caution, some plaintiffs took a conservative approach and filed claims under the Tennessee Products Liability Act before the one year anniversary of their injury while waiting for their Healthcare Liability Act claims to ripen. Many of those original products liability complaints expressly stated they did not contain claims under the Healthcare Liability Act, and many plaintiffs explicitly reserved their right to amend their pleadings to add claims under the Healthcare Liability Act, once such claims became ripe.[6] The plaintiffs then amended their complaints to add claims under the Healthcare Liability Act, and they filed all documents required by the Healthcare Liability Act with their amended complaints.[7]

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[4] *See* Tenn. Code Ann. § 29-26-116 citing Tenn. Code Ann. § 28-3-104 (imposing one year statute of limitations for claims under the Healthcare Liability Act).
[5] Tenn. Code Ann. § 29-26-121(c).
[6] *See e.g.*, Complaint ¶¶ 255-258, *Barger v. Ameridose*, Case No. 1:13-cv-12619 (discussing reasons for filing only claims under the TPLA and awaiting sixty day period to run under Tenn. Code Ann. § 29-26-121) (hereinafter "Barger Complaint"); Complaint ¶ 172, *Minor v. Ameridose*, Case No. 1:13-cv-12836 (declining to assert claims under the Healthcare Liability Act and reserving right to amend to add claims later) (hereinafter "Minor Complaint").
[7] *See e.g.*, Amended Complaint, *Barger v. Ameridose*, Case No. 1:13-cv-12619 (hereinafter "Barger Amended Complaint"); Amended Complaint, *Minor v. Ameridose*, Case No. 1:13-cv-12836 (hereinafter "Minor Amended Complaint").

IV. Factual Background

The facts supporting the Tennessee plaintiffs' claims are discussed at length in the Tennessee plaintiffs' Response in Opposition to the Tennessee Defendants' Motion to Dismiss Global Claims.[8] Those facts are incorporated herein by reference and need not be repeated in this filing.

V. Argument

The Saint Thomas Entities seek dismissal of cases identified in the case caption on the specious and unsupported ground that those plaintiffs' original complaints, which stated claims only under the Products Liability Act, were nevertheless required to comply with provisions under the altogether separate and distinct Healthcare Liability Act. Specifically, the Saint Thomas Entities seek dismissal on the incorrect and hyper-technical ground that plaintiffs filing only products liability actions must comply with the Healthcare Liability Act's pre-suit notice requirements of Tenn. Code Ann. § 29-26-121 and certificate of good faith requirement of Tenn. Code Ann. § 29-26-122. Both arguments fail for several reasons.

First, plaintiffs' claims under the Product Liability Act are "product liability actions" and not "healthcare liability actions." Therefore, those claims are not subject to the pre-suit notice and certificate faith requirements contained in the Healthcare Liability Act. Second, even if the pre-suite notice requirements apply (which they do not), dismissal is not appropriate unless and until the Saint Thomas Entities demonstrate actual prejudice resulting from plaintiffs' alleged technical deficiencies. Third, with regard to the certificate of good faith requirement, even if plaintiffs' product liability claims could be construed as "healthcare liability actions" (which they cannot), those claims are certainly not the type of "healthcare liability actions" that require a certificate be filed.

[8] Doc. 1040.

Finally, the Saint Thomas Entities' Motion is completely incompatible with federal procedural law. Under the Federal Rules of Civil Procedure, plaintiffs are entitled to alternatively plead products liability claims separate and apart from any healthcare liability claims and the Healthcare Liability Act cannot alter, amend, or curtail plaintiffs' right to plead claims in the alternative.[9] Accordingly, the Saint Thomas Entities' Motion has no merit under either Tennessee law and/or federal procedural law, and the Motion must be denied.

a. Plaintiffs Filing Only Products Liability Actions Are Not Required To Comply With The Pre-Suit Notice Requirements Of Tenn. Code Ann. § 29-26-121 And Even If They Were, The Saint Thomas Entities Have Failed To Demonstrate Any Prejudice From Any Technical Failures To Comply With Tenn. Code Ann. § 29-26-121.

i. Plaintiffs' Product Liability Claims Are "Product Liability Actions" And Not "Healthcare Liability Actions"

Claims under the Products Liability Act exist independent and apart from any potential claims under the Healthcare Liability Act. The Products Liability Act broadly defines a "product liability action" as "***all actions*** brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging or labeling of ***any product***."[10] Under the Product Liability Act, a "seller" is defined to include "a retailer, wholesaler, or distributor, and means any individual or entity engaged in the business of selling a product, whether such sale is for resale, or for use or consumption…"[11] In the present case, plaintiffs originally asserted product liability claims against certain clinic defendants only in their capacities as "sellers" under the Products Liability Act for the personal injuries arising from the defective product sold to them by these defendants.

[9] It is undisputed that all cases subject to the Motion have now fully satisfied via an amended pleading all requirements of Tenn. Code Ann. § 29-26-121 and 122.
[10] Tenn Code Ann. § 29-28-102(6).
[11] Tenn. Code Ann. § 29-28-102(7).

Tennessee law clearly provides that claims arising from injuries from pharmaceuticals arise under the Products Liability Act. The Sixth Circuit, in addressing that very issue, stated:

> The Tennessee Products Liability Act governs products liability actions in Tennessee and defines product liability actions as all actions brought for or on account of personal injury, death, or property damage caused by or resulting form the manufacture, construction, design, formula, preparation, assembly, testing, service, warning instruction, marketing, packing or labeling of any product. The TPLA also encompasses several different theories of products liability: strict liability in tort; negligence; breach of warranty, express or implied, breach of or failure to discharge a duty to warn or instruct, whether negligent or innocent; misrepresention, concealment or nondisclosure, whether negligent or innocent; ***or under any other substantive legal theory in tort or contract whatsoever***.[12]

The Sixth Circuit went on to hold in *Strayhorn* that "the [Products Liability Act] governs all of plaintiffs' claims because the claims were brought for or on account of personal injury resulting from the design, warning, instruction, marketing, packaging, and labeling of [a pharmaceutical]." *Id*. That holding is hardly isolated. The notion that claims for injuries resulting from exposure to pharmaceuticals are "product liability actions" under the Products Liability Act enjoys near universal acceptance among reviewing courts.[13]

In the present cases, plaintiffs' product liability claims arise from the defective and unreasonably dangerous condition of a pharmaceutical product, specifically contaminated epidural steroids. Those product liability claims do not arise from the services performed while

[12] *Strayhorn v. Wyeth Pharma., Inc.*, 737 F.3d 378, 392 (6th Cir. 2013). This is not to say that Product Liability Act is exclusive and precludes liability based on the alternative ground of negligence of the seller when it can be proven. *Corporate Air Fleet of Tennessee, Inc. v. Gates Learjet, Inc.*, 589 F.Supp. 1076 (6th Cir. 1984). In other words, plaintiffs can simultaneously pursue claims that defendants are liable in strict liability for selling an unreasonably dangerous product and are also liable for their negligent conduct in dispensing a tainted pharmaceutical to plaintiffs. This type of alternative pleading is clearly permitted under Rule 8(e)(2), as discussed at greater length below.

[13] *See e.g.*, *Montgomery v. Wyeth*, 580 F.3d 455 (6th Cir. 2009) (applying Products Liability Act to personal injuries suffered from exposure to pharmaceutical); *Mathis v. Eli Lilly & Co.*, 719 F.2d 134 (6th Cir. 1983) (same); *Payne v. Novartis Pharms. Corp.*, 967 F. Supp. 2d 1223 (E.D. Tenn. 2013); *Pittman v. Upjohn Co.*, 890 S.W.2d 425 (Tenn 1994); *Baker v. Lederle Laboratories*, 696 S.W.2d 890 (Tenn. Ct. App. 1985); *Witherspoon v. Ciba-Geigy Corp.*, 1986 Tenn. App. LEXIS 2773 (Tenn. Ct. App. 1986).

administering that product to the patients. Specifically, plaintiffs' product liability claims allege:

> 162. The MPA that Saint Thomas Neurosurgical and Howell Allen Clinic injected into Plaintiff's lumbar spine was unreasonably dangerous and defective at the time it was administered because it was contaminated with lethal pathogens.
>
> 163. Specifically, the MPA was in a defective condition and unreasonably dangerous at all relevant times because it was unsafe for normal or anticipated handling as defined by Tenn. Code Ann. § 29-28-102(2).
>
> 164. The MPA sold and distributed by Saint Thomas Neurosurgical and Howell Allen Clinic was neither merchantable nor fit for the purpose for which it was produced and sold. Accordingly, Saint Thomas Neurosurgical and Howell Allen Clinic breached its warranties, both express and implied, as stated in Tenn. Code Ann. §§ 47-2-313, 47-2-314 and 47-2-315, including its warranty of fitness for a particular purpose.
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> 165. Saint Thomas Neurosurgical and Howell Allen Clinic are strictly liable for the injuries and losses caused by the unreasonably dangerous and defective steroids injected into Plaintiff's lumbar spine.[14]

Those allegations clearly demonstrate that Plaintiff's product liability actions relate solely to the defective and dangerous condition of the contaminated steroids sold to the plaintiffs by the defendants. "[T]he key inquiry in all products liability cases is whether or not there is a defect, it is the product, and not the defendant's conduct, that is on trial."[15] Plaintiffs' product liability claims are limited to harm caused by the product itself unrelated to the manner and provision of the healthcare services provided by the Defendants.[16]

On the other hand, the Healthcare Liability Act, by its express terms, applies only to

[14] *See* Barger Complaint; Minor Complaint.
[15] 63 Am Jur 2d Products Liability § 6; *see also*
[16] In fact, most of the complaints subject to this Motion specifically disclaimed any claims for healthcare liability and reserved the right to bring those claims once they ripened. *See e.g.*, Barger Complaint, ¶ 255 ("The Plaintiffs reserve the right to amend this complaint…to add their causes of action pursuant to Tenn. Code Ann. § 29-26-*et seq.* once the required 60 days has lapsed."); Minor Complaint, ¶ 172 ("Out of an abundance of caution, neither this claim, nor any other claim or count asserted in this action, is meant to allege a claim arising under or otherwise covered by the [Healthcare Liability Act].")

healthcare *services*, not products sold by healthcare providers. Importantly, Section 101 of the Healthcare Liability Act defines a "health care liability action" in terms of claims arising from the provision of "health care services," not the sale or distribution of goods or products. The Healthcare Liability Act states:

> "Health care liability action" means any civil action, including claims against the state or a political subdivision thereof, alleging that a health care provider or providers have caused an injury related to the provision of, or failure to provide, health care services to a person, regardless of the theory of liability on which the action is based.[17]

The statute specifically defines "health care services" as follows:

> Health care services to persons includes care by health care providers, which includes care by physicians, nurses, licensed practical nurses, pharmacists, pharmacy interns or pharmacy technicians under the supervision of a pharmacist, orderlies, certified nursing assistants, advance practice nurses, physician assistants, nursing technicians and other agents, employees and representatives of the provider, and also includes staffing, custodial or basic care, positioning, hydration and similar patient services.[18]

Nowhere does the statute say that "health care services" include products sold or distributed by healthcare providers. In fact, the words "goods," "product," and/or "products" never appear anywhere in the entire Healthcare Liability Act.

In short, Plaintiff's originally filed complaints alleged only "product liability actions" under the Tennessee Products Liability Act, not "healthcare liability actions" under the Healthcare Liability Act. Therefore, plaintiffs were not required to comply with the pre-suit notice requirements contained in Tenn. Code Ann. § 29-26-121 prior to filing those "product liability actions." The Saint Thomas Entities fail to cite to a single case holding to the contrary. The Saint Thomas Entities likewise fail to offer any authority altering the long standing rule in

[17] Tenn. Code Ann. § 29-26-101(a)(1).
[18] Tenn. Code Ann. § 29-26-101(b).

Tennessee that claims arising from exposure to a pharmaceutical are "product liability actions" as that term is used in Tenn. Code Ann. § 29-28-102(7).

As the "manufacturer" of the MPA that killed and injured numerous Tennessee plaintiffs, NECC, like the many other pharmaceutical companies before it, would be subject to suit under the Tennessee Products Liability Act.[19] However, once NECC was judicially declared insolvent, then plaintiffs' claims against the "sellers" of that defective product then ripened.[20] The Saint Thomas Entities would have this Court believe that product liability claims magically transformed into "healthcare liability actions" once NECC became insolvent and strict seller liability under the Tennessee Product Liability Act was triggered. *See* Tenn. Code Ann. § 29-28-106(5).

ii. Even If Notice Were Required, Strict Compliance with the Various Technical Requirements of Tenn. Code Ann. § 29-26-121 is not Required and Prejudice Must be Shown Before a Lawsuit is Dismissed.

As explained above, plaintiffs' claims alleging only product liability are "product liability actions" and not "healthcare liability actions." However, even if those claims could be construed as falling under the Healthcare Liability Act (which they do not), plaintiffs' claims would still not be subject to dismissal.

The Saint Thomas Entities make the overly broad, and thus incorrect, assertion that in the case of *Myers v. AMISUB (SFH), Inc.*, 382 S.W.3d 300 (Tenn. 2012), the Tennessee Supreme Court held that the requirements of Tenn. Code Ann. § 29-26-121 are mandatory.[21] Those Defendants also incorrectly assert: (1) that they do not have to prove prejudice in order to obtain dismissal of an injured Plaintiff's complaint, and (2) that substantial compliance with the statute

[19] *See e.g., Strayhorn*, 737 F.3d at 392 (discussing applicability of Products Liability Act to claims brought as a result of injury from exposure to pharmaceutical).
[20] *See* Tenn. Code Ann. § 29-28-106(5).
[21] Defendants' Memorandum, Doc. 898, p. 9.

cannot satisfy the technical requirements of Tenn. Code Ann. § 29-26-121. The Tennessee Defendants attempt to support those incorrect assertions by citing four unpublished decisions in a footnote that have since been contradicted by the Tennessee Supreme Court.[22] As explained below, there are several problems with the Defendants' assertions.

First, the *Myers* Court did not state that strict compliance with the technical requirements of Tenn. Code Ann. § 29-26-121 is mandatory. Instead, the Court carefully limited its decision to hold only that, in a health care liability action, the statutory requirements that a plaintiff give pre-suit notice [per Tenn. Code Ann. § 29-26-121] and file a certificate of good faith [per Tenn. Code Ann. § 29-26-122] with a complaint are mandatory. The *Myers* Court deliberately left for another day the question of whether the technical requirements of Tenn. Code Ann. § 29-26-121 could be satisfied by substantial compliance.[23]

The Tennessee Supreme Court has now clarified this question in two key decisions. In *Stevens v. Hickman Community Health Care Services, Inc., et al.*, 418 S.W.3d 547 (Tenn. 2013) (copy attached hereto as Exhibit 1) the Tennessee Supreme Court made clear that: (1) substantial compliance with the technical requirements of Tenn. Code Ann. § 29-26-121 is sufficient; and (2) a complaint should not be dismissed based upon a statutory technicality unless and until a defendant shows actual prejudice.

In addition, more recently in *Thurmond v. Mid-Cumberland Infectious Disease Consultants*, 2014 Tenn. LEXIS 352 (Tenn. Apr. 24, 2014), the Tennessee Supreme Court once again reiterated its stance that before a suit can be dismissed for failure to comply with Tenn. Code Ann. § 29-26-121, a defendant must demonstrate actual prejudice resulting from any

[22] *Id.*, p. 9, and fn 24.
[23] *Myers*, 382 S.W.3d at 310 ("[W]e need not decide whether the statutes' requirements as to the content of the notice and the certificate of good faith may be satisfied by substantial compliance.")

technical deficiencies.[24] Here, the Saint Thomas Entities have not attempted to demonstrate, nor could they demonstrate, that they have been prejudiced by any failure of plaintiffs to comply with Tenn. Code Ann. § 29-26-121. The Saint Thomas Entities merely seek to dismiss these cases on a hyper technical reading of a statute that is unsupported by the relevant case law. In fact, the Saint Thomas Entities improperly rely upon the Court of Appeals decision in *Thurmond* for their claims that Section 121's requirements must be strictly enforced. However, since the filing of their Motion, the Tennessee Supreme Court overturned that decision all but destroying the foundation of the Saint Thomas Entities' position.

Taken together, *Stevens* and *Thurmond* require that before this Court can dismiss any Plaintiff's claims, it must conduct a case specific inquiry about whether the Plaintiff substantially complied with the requirements of Tenn. Code Ann. § 29-26-121(a). As explained by the Tennessee Supreme Court in *Stevens*, the purposes of the pre-suit notice requirements articulated in Tenn. Code Ann. § 29-26-121(a) include: (1) requiring plaintiffs to notify health care Defendants of impending litigation before it occurs, (2) facilitating settlement negotiations by informing target defendants of upcoming litigation so that pre-suit settlements can occur, and (3) allowing target health care defendants to investigate potential claims by gathering medical records from other parties being sent notice.[25]

In fact, Plaintiffs demonstrated compliance with Tenn. Code Ann. 29-26-121's pre-suit notice requirements when they filed their amended complaints asserting, for the first time, claims under the Healthcare Liability Act. Accordingly, it is without question that those plaintiffs complied with the letter and spirit of Tenn. Code Ann. §§ 29-26-121 as demonstrated by their amended pleadings.

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[24] *Thurmond*, 2014 Tenn. LEXIS 3521, overturning grant of motion to dismiss where Defendant "[made] no claim of prejudice" resulting from Plaintiff's failure to comply with Tenn. Code Ann. § 29-26-121.
[25] *Stevens*, 418 S.W.3d at 554.

In spite of the fact that each of those plaintiffs demonstrated compliance with Section 121 in their amended pleadings, the Saint Thomas Entities nevertheless claim that those plaintiffs' claims should be summarily dismissed because the original complaints failed to strictly comply with Section 121. Such a result would be contrary to the substantial compliance and actual prejudiced requirements articulated in *Stevens*, 418 S.W.3d at 554-556, and it would violate basic precepts of justice.

Suffice it to say that this Court should not summarily dismiss any plaintiffs' claim before conducting a careful review of that particular Plaintiff's pleadings in order to determine whether they substantially complied with the statute and whether the Defendants suffered any actual prejudice. In addition, no case should be dismissed before the injured plaintiff is given an opportunity to be heard on the issue of substantial compliance.

Furthermore, before this Court dismisses any claim based upon a violation of Tenn. Code Ann. § 29-26-121, it must determine whether extraordinary cause exists for excusing the subject violation.[26] Such a determination can only be made after the Court conducts a case specific inquiry affording individual plaintiffs with the opportunity to be heard regarding mitigating factors, circumstances surrounding the particular violation, and why their claims should not be dismissed.[27] Therefore, if this Court determines that any violation of Tenn. Code Ann. § 29-26-121 occurred, the proper procedure is not to dismiss in its entirety an injured Plaintiff's case automatically. The Plaintiff must be given the opportunity to be heard on the issue of extraordinary cause. Therefore, the subject motion must be denied.

b. Plaintiffs Filing Only Products Liability Actions Are Not Required To File A Certificate Of Good Faith Under Tenn. Code Ann. § 29-26-122.

The Saint Thomas Entities also incorrectly assert that cases initially asserting only

[26] *See* Tenn. Code Ann. § 29-26-121(b) and Tenn. Code Ann. § 29-26-122(a).
[27] *See generally Myers*, 382 S.W. 3d at 307 and *Stevens*, 418 S.W.3d at 556-557.

product liability claims must be dismissed for failure to file the certificate of good faith as required by Tenn. Code Ann. § 29-26-122. This position is clearly at odds with the plain language of that statute. In relevant part, Tenn. Code Ann. § 29-26-122 states:

> ***In any health care liability action in which expert testimony is required by § 29-26-115***, the plaintiff or plaintiff's counsel shall file a certificate of good faith with the complaint. (emphasis added).

Tenn. Code Ann. § 29-26-115 addresses plaintiff's burden, in a medical malpractice case, of proving a breach of the standard of care in the provision of healthcare services.[28] Therefore, as is clear from the above-quoted language, a certificate of good faith under Tenn. Code Ann. § 29-26-122 is required if and only if two prerequisites are satisfied: 1) the plaintiff has asserted a claim constituting a "health care liability action"; and 2) the claim requires expert proof related to defendant's breach of the standard of care.

Plaintiffs' claims under the Products Liability Act fail both preconditions: 1) Plaintiffs' Product Liability Act claims are not "healthcare liability actions" but rather "product liability actions"; and 2) those claims do not require expert testimony as to a breach of the applicable standard of care.

Plaintiffs have already demonstrated that their product liability claims are "product liability actions" and not "healthcare liability actions."[29] Moreover, it is axiomatic that a claim for strict product liability under the Products Liability Act does not require proof of a breach of the standard of care. The Tennessee Supreme Court has held:

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[28] In a healthcare liability action, the claimant shall have the burden of proving by evidence as provided by subsection (b): (1) The recognized standard of acceptable professional practice in the profession and the specialty thereof, if any, that the defendant practices in the community in which the defendant practices or in a similar community at the time the alleged injury or wrongful action occurred; (2) That the defendant acted with less than or failed to act with ordinary and reasonable care in accordance with such standard; and (3) As a proximate result of the defendant's negligent act or omission, the plaintiff suffered injuries which would not otherwise have occurred. Tenn.Code Ann. § 29-26-115.

[29] *See* discussion *supra* at 6-10.

> Strict liability in tort is recognized as a cause of action in the Tennessee Products Liability Act of 1978, Tenn. Code Ann. §§ 29-28-101 to 29-29-108 (1980 and Supp. 1994). Under Tenn. Code Ann. § 29-28-105(a) (1980), a manufacturer or seller of a product may be liable for injury to person or property caused by the product if the product is determined to be in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller. ***Proof of negligence on the part of the manufacturer or seller is not required***.[30] (emphasis added).

The very purpose of strict liability is to relieve the plaintiff of his duty to prove a breach of a duty of care:

> We imposed strict liability against the manufacturer and in favor of the user or consumer in order to relieve injured consumers 'from problems of proof inherent in pursuing negligence . . . and warranty . . . remedies . . .' As we have noted, we sought to place the burden of loss on manufacturers rather than 'injured persons who are powerless to protect themselves.[31]

Clearly, claims arising under the Products Liability Act are not claims that "require expert testimony required by Tenn. Code Ann. § 29-26-115."[32]

Given the plain language of the statute, Saint Thomas Entities overly simplistic assertion that "Section 29-26-122 requires plaintiffs to file a certificate of good faith with the complaint" is wholly unsupported. The Saint Thomas Entities cannot identify a single judicial opinion in which a plaintiff's claims for product liability have been dismissed for failure to attach a certificate of good faith as contemplated by Tenn. Code Ann. § 29-26-122. Instead, the Saint Thomas Entities cite to a case that reveals the utter futility to their argument. In *Moses v. Dirghangi*, 2013 Tenn. App. LEXIS 661 (Tenn. Ct. App. Oct. 3, 2013). In *Moses*, the Tennessee Court of Appeals held that:

> The primary consideration in a medical battery case is simply whether the patient knew of and authorized a procedure. This

[30] *Owens v. Truckstops of Am.*, 915 S.W.2d 420 (Tenn. 1996) (emphasis added.)
[31] *Id*. (internal citations and quotations omitted).
[32] Tenn. Code Ann. § 29-26-122.

> determination does not require the testimony of an expert witness. ***Because a medical battery claim does not require expert proof, a plaintiff bringing this claim is not required to file a certificate of good faith pursuant to the [Healthcare Liability Act]***.[33]

Like medical battery, claims under the Product Liability Act do not require expert proof and a "plaintiff bringing this claim is not required to file a certificate of good faith pursuant to the [Healthcare Liability Act]."[34]

Accordingly, plaintiffs did not need to file a certificate of good faith under Tenn. Code Ann. § 29-26-122 to assert claims under the Products Liability Act.

c. Plaintiffs Have The Absolute Right To Plead Alternative Claims And Amend Their Complaint To Bring Claims In The Alternative.

For the reasons explained above, the Saint Thomas Entities' request to dismiss plaintiffs' original complaints is wholly without merit. Those original complaints contained product liability claims only, and they were not subject to the requirements of the Healthcare Liability Act. However, even assuming *arguendo* that plaintiffs' products liability claims could somehow be subject to the pre-suit notice and/or the certificate of good faith requirements contained in the Healthcare Liability Act, plaintiffs were nevertheless entitled to alternatively plead their products liability claims as falling outside of the scope of the Healthcare Liability Act.[35]

"Under Rule 8(e)(2) of the Federal Rules of Civil Procedure, a plaintiff may plead two or

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[33] *Id*. at *11 citing *Hinkle v. Kindred Hosp., No*. 2012 Tenn. App. LEXIS 611, at *17, n.11 (Tenn. Ct. App. Aug. 31, 2012) ("Since expert testimony is not required to sustain a claim for medical battery, we concluded that the certificate need not be filed to support such claims.").

[34] *Id*.

[35] The Saint Thomas Entities appear to base this position on the definition of "Health care liability action" which "means any civil action, including claims against the state or a political subdivision thereof, alleging that a health care provider or providers have caused an injury related to the provision of, or failure to provide, health care services to a person, *regardless of the theory of liability on which the action is based*." Tenn. Code Ann. § 29-26-101(a)(1) (emphasis added). Under the Saint Thomas Entities' theory, the language "regardless of the theory of liability" requires that plaintiffs asserting claims for personal injury damages against healthcare providers must bring a "health care liability action" and the requirements of Section 121 and 122 apply. Even if this were the case, and based on the discussion *supra* it clearly is not, under Rule 8(e), plaintiffs would have the right to plead its product liability claims are "products liability actions" as that term is defined in Tenn. Code Ann. § 29-28-101.

more statements of a claim, even within the same count, regardless of consistency."[36] "The inconsistency may lie either in the statement of the facts or in the legal theories adopted."[37] In other words, plaintiffs are entitled under Rule 8 to state a claim under the Products Liability Act and plead that it falls outside of coverage under the Healthcare Liability Act as they did here.

The Saint Thomas Entities' position that all claims brought against healthcare providers must be "healthcare liability actions" and therefore comply with Sections 121 and 122 is simply at odds with the alternative pleading rules of Rule 8, which is specifically designed to afford a federal litigant pleading flexibility. As one federal court succinctly stated in the context of an ERISA action:

> The reason for employing alternative pleading in cases under the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C.S. § 1001 et seq., is plain enough. Given the uncertainties concerning whether the plan in question is an ERISA plan and the scope of ERISA preemption, it would be foolish to put all of one's eggs in either the ERISA or the state law basket. Fed. R. Civ. P. 8(e)(2) permits such alternative pleading to avoid precisely such dilemmas.[38]

In other words, under Rule 8, plaintiffs were not required to place all of their eggs in the "Healthcare Liability Act" basket. They had an absolute right under Rule 8 to alternatively plead claims under the Product Liability Act.[39]

Furthermore, plaintiffs' right to plead in the alternative cannot be altered or changed or

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[36] *Riverwoods Chappaqua Corp. v. Marine Midland Bank*, 30 F.3d 339, 343 (2d Cir. 1994) ("[A] party may properly submit a case on alternative theories."); *see also Brody v. Stone & Webster, Inc.*, 414 F.3d 187, n. 8 (1st Cir. 2005) ("A plaintiff has the right to plead in the alternative, and the plaintiff's doing so does not undermine the validity of the complaint.")

[37] *Id*. citing 2A JAMES W. MOORE & JO D. LUCAS, MOORE'S FEDERAL PRACTICE P 8.32, at 8-214 to 8-215 (2d ed. 1994)

[38] *Coleman v. Std. Life Ins. Co.*, 288 F. Supp. 2d 1116, 1121 (E.D. Cal. 2003) quoting *Aiena v. Olsen*, 69 F. Supp.2d 521, 531 (S.D.N.Y. 1999). ; *see also MacFarlane v. Grasso, 696 F.2d 217, 224-25 (2d Cir. 1982)* (holding that § 1983 plaintiff conceded existence of disputed agency policy only to the extent that he challenged the constitutionality of that policy, but not for purposes of other claims); *Wright v. Olin Corp.*, 697 F.2d 1172, 1184 (4th Cir. 1982) ("It is often appropriate to assess particular Title VII claims and defenses alternatively under different theories.").

[39] *Coleman*, 288 F.Supp. 2d at 1121.

amended by the Healthcare Liability Act, even if the Healthcare Liability Act is considered "substantive" as the Saint Thomas Entities allege.[40] Here, to the extent that the Healthcare Liability Act would prevent a federal litigant from pleading alternative claims of liability, it would not apply to claims brought in federal court.

It is well settled that, when a state substantive law conflicts with a controlling Federal Rule of Civil Procedure, the federal courts ***must*** apply the Federal Rule unless that rule exceeds the mandate embodied in the Rules Enabling Act or transgresses constitutional bounds.[41] Specifically, the United States Supreme Court held in *Hanna* that:

> To hold that a Federal Rule of Civil Procedure must cease to function whenever it alters the mode of enforcing state-created rights would be to disembowel either the Constitution's grant of power over federal procedure or Congress' attempt to exercise that power…[42]

In other words, "when a Federal Rule of Civil Procedure is on point, it, not the state law, governs so long as it does not run afoul of the Rules Enabling Act or the Constitution."[43]

The Saint Thomas Entities' position that a plaintiff cannot plead claims under the Products Liability Act as existing outside of the Healthcare Liability Act incorrectly urges the same "disemboweling" of the Federal Rule of Civil Procedure that the *Hanna* court rejected by limiting a litigant's right to plead claims in the alternative. Even if the Healthcare Liability Act

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[40] Dkt. No 780, Memo in Support at P. 4 ("The notice and certificate requirements of the [Healthcare Liability Act] are 'substantive law' and thus apply in federal court as well.") (internal citations omitted).

[41] *Hanna v. Plumer*, 380 U.S. 460, 463-64, (1965); *see Burlington Northern R. Co. v. Woods*, 480 U.S. 1, 4-5 (1987); *Shady Grove Orthopedic Assocs. v. Allstate Ins. Co.*, 559 U.S. 393 (2010); *McCalla v. Royal MacCabees Life Ins. Co.*, 369 F.3d 1128, 1135 (9th Cir. 2004) ("[W]hen a Federal Rule of Civil Procedure is on point, it, not the state law, governs, so long as it does not run afoul of the Rules Enabling Act" or the Constitution."); *see also Davis v. Piper Aircraft Corp.*, 615 F.2d 606, 611 (4th Cir. 1980) (applying Fed. R. Civ. P. 15(c) rather than contrary North Carolina law regarding relation back of amended pleadings).

[42] *Hanna*, 380 U.S. at 473. *see also Shady Grove*, 130 S. Ct. at 1437 (if Federal Rule of Civil Procedure "answers the question in dispute…it governs, [state] law notwithstanding-unless it exceeds statutory authorization or Congress's rulemaking power.").

[43] *McCalla*, 369 F.3d at 1135; *see also Piper Aircraft Corp., 615 F.2d 606, 611 (4th Cir. 1980); see also Willever v. United States,* 775 F. Supp. 2d 771, 781 (D. Mary. 2011)("[W]here a state statute imposes greater procedural burdens on a party than does a Federal Rule of Civil Procedure, and the statute and rule govern the same issue, the state statute cannot be applied in federal court.").

prevented plaintiffs from asserting claims under the Product Liability Act without first complying with Sections 121 and 122, the Healthcare Liability Act simply cannot change the right of a federal litigant to plead in the alternative that those products liability claims fall outside of Section 121 and 122's requirements.[44]

As explained above, certain plaintiffs first filed claims under the Product Liability Act to ensure those claims were timely filed under the relevant statute of limitations. They pled those original claims as falling outside of the coverage of the Healthcare Liability Act (i.e. they pled that pre-suit notice and certificate of good faith did not apply to those claims).[45] Thereafter, once claims under the Healthcare Liability Act ripened, plaintiffs amended their complaints to assert claims under the Healthcare Liability Act (i.e. medical malpractice) as well as claims under the Products Liability Act (i.e. strict products liability). Because Rule 8(e) allows plaintiffs to "plead two or more statements of a claim, even within the same count, regardless of consistency,"[46] plaintiffs could plead that their claims under the Products Liability Act existed outside of the Healthcare Liability Act and simultaneously claim certain other claims were subject to the Healthcare Liability Act.[47] That type of alternative pleading is especially appropriate when, as here, plaintiffs' claims raise complex legal issues that justify raising multiple, inconsistent claims.[48]

There can be little doubt that Rule 8(e) is a valid federal procedural rule and that it "controls" the issue of whether plaintiffs bringing products liability claims can plead that basis of relief alternatively from any potential claims under the Healthcare Liability Act. Therefore, to

[44] *Henry*, 4 F.3d at 95 ("Under Rule 8(e)(2) of the Federal Rules of Civil Procedure, a plaintiff may plead two or more statements of a claim, even within the same count, regardless of consistency.")
[45] *See e.g.*, Barger Complaint, at ¶¶ 255- 258; Minor Complaint, at ¶ 172.
[46] *Id.*
[47] *See id.* citing *Riverwoods Chappaqua Corp. v. Marine Midland Bank*, 30 F.3d 339, 343 (2d Cir. 1994) ("[A] party may properly submit a case on alternative theories.").
[48] *See, e.g.*, *MacFarlane v. Grasso*, 696 F.2d 217, 224-25 (2d Cir. 1982); *Wright v. Olin Corp.*, 697 F.2d 1172, 1184 (4th Cir. 1982); *Coleman*, 288 F. Supp. 2d at 1121.

the extent that it conflicts with state law, even state substantive law, the federal procedural rule must prevail.[49]

The practical import of this distinction has significant bearing on the Motion. Here, even if the Court were to rule that plaintiffs' products liability claims as originally pled were subject to the Healthcare Liability Act's pre-suit notice and certificate of good faith requirements, those claims would not be subject to dismissal because an alternatively pled claim "is not made insufficient by the insufficiency of one or more of the alternative statements."[50] In other words, even if plaintiffs' originally pled products liability claims are subject to dismissal because of failure to satisfy Section 121 and 122 requirements, plaintiffs' amended alternative claims which comply with those statutes survive. Rule 8 compels such a result, and the Healthcare Liability Act cannot change it.

CONCLUSION

For the forgoing reasons the Saint Thomas Entities Motion to Dismiss must be denied to the extent that it seeks to dismiss all claims brought by plaintiffs who first pled only claims under Tennessee's Products Liability Act.

Dated: May 9, 2014

Respectfully submitted,

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[49] *See e.g.*, *Atlantic Richfield Co. v. Monarch Leasing Co.*, 80 F.3d 204 (6th Cir. 1996); *Piper Aircraft Corp.*, 615 F.2d at 611; *see also Willever*, 775 F. Supp. 2d at 780-81 (refusing to apply state medical malpractice pre-suit expert certification requirements when they conflicted with Rule 26 of the Federal Rules of Civil Procedure).

[50] *In re Methyl Tertiary Butyl Ether (MTBE) Prods. Liab. Litig.*, 415 F. Supp. 2d 261, 274 (S.D.N.Y. 2005) quoting Fed. R. Civ. P. 8(e).

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CERTIFICATE OF SERVICE

I, J. Gerard Stranch, IV, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: May 9, 2014

/s/ J. Gerard Stranch, IV
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